

Amendment and Response
Applicants: Kevin J. Kollar et al.
Serial Number: 09/963,793

Attorney Docket: CV0291US

REMARKS

Claims 1- 3 and 5-10 are pending. Claim 6 was previously amended. Claims 1, 5 and 10 are presently amended. Claim 4 is cancelled. Claims 2, 3 and 7 - 9 are original.

Claims 1-10 have all been newly rejected under 35 U.S.C. 102(b) over U.S. Pat. No. 4,479,762, Bilstad, et al. ("Bilstad II"). The rejection of claim 4 is moot with the cancellation thereof. Claims 1, 6 and 7 have been newly rejected under 35 U.S.C. 102(b) over U.S. Pat. No. 5,423,749, Merte, et al. ("Merte"). Claims 1-3 and 6-8 have been newly rejected under 35 U.S.C. 102(e) over U.S. Pat. No. 6,632,189, Fallen, et al. ("Fallen"). In order for a reference to anticipate a claim, that reference must have all elements of the claim arranged as they are in the claim. Applicants respectfully submit that, with the present amendments, none of Bilstad II, Merte and Fallen anticipates any of the pending claims.

Anticipation requires that the identical invention that is claimed was previously known to others and thus is not new. The Examiner's burden is to show that the asserted anticipating references identically describe every element of the rejected claims. That is, the Examiner must show that Bilstad II anticipates every element of claims 1-3 and 5-10, that Merte anticipates every element of claims 1, 6 and 7, and that Fallen anticipates every element of claims 1-3 and 6-8. Terms of prior art patents are construed as the patentees used them. Anticipation also requires that the prior art must be such that a person of ordinary skill in the field of the invention would consider there to be no difference between the claimed invention and the reference disclosure. The prior art reference must put the claimed invention in the hands of one skilled in the art. The prior art reference must describe the applicant's claimed invention sufficiently to have placed a

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person of ordinary skill in the field of the invention in possession of it. The present rejections are in error and must be withdrawn.

Bilstad II describes a prepackaged fluid processing module that may be disposable. Bilstad II exemplifies the module as useful for blood fractionation procedures, such as plasmapheresis, leukopheresis, plateletpheresis, and similar procedures. Bilstad II broadly states that "[t]he prepackaged, easily handled module 20 ... [is] suited for use with virtually any fluid system." Bilstad II, col. 4, lines 55-57. However, Bilstad II does not teach or suggest alone or with any other record reference that the Bilstad II module may be useful in an extracorporeal blood perfusion system, as required by the present claims. Bilstad II does not teach or suggest, alone or with any other record reference, that the Bilstad II module may have "an internal cardiopulmonary passageway being configured for operative connection to the cardiopulmonary circuit, an internal cardioplegia passageway being configured for operative connection to the cardioplegia circuit and an internal suction passageway being configured for operative connection to the suction circuit" as present claim 1 requires. Claims 2, 3 and 5-10 add further patentable features that further distinguish over Bilstad II. Accordingly, Bilstad II does not anticipate or render obvious the present claims.

Merte describes a disposable cassette system for use with a system that administers only cardioplegia. Merte does not teach or suggest, alone or in connection with any other record reference that the Merte cassette may be useful in an extracorporeal blood perfusion system, as is the presently claimed cartridge. Merte does not teach or suggest, alone or in connection with any other record reference, that the Merte cassette may have "an internal cardiopulmonary passageway being configured for operative connection to the cardiopulmonary circuit ... and an internal suction passageway being configured for operative

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connection to the suction circuit” as the present claims require. The Merte cassette has an internal cardioplegia passageway configured for operative connection to a cardioplegia circuit in the cardioplegia administration system. “The cassette 200 comprises a box-like frame containing a three-way connector 206 joining the cardioplegia supply tube 108, the blood supply tube 116, and the recirculation tube 126, all to the cardioplegia administration tube 124, as shown in FIG. 9.” Merte, col. 7, lines 18-23. The Merte cassette does have a pressure line, but does not provide suction to withdraw blood or fluids from the patient or surgical site, as the present claims require. Rather, the Merte cassette pressure line measures the pressure of the cardioplegia solution in the cardioplegia administration tube. “The cassette 200 may also include a pressure line 151 extending to the pressure transducer 150.” Merte, col. 7, lines 23-24. “The ... pressure transducer 150 [is] connected to the controller 148 with a pressure line 151 that monitors the pressure of the cardioplegia solution in the cardioplegia administration tube 124, and provides this information to the controller 148.” Merte, col. 6, lines 23-28. Claims 6 and 7 add patentable features that distinguish over Merte. Accordingly, Merte does not anticipate or render obvious present claims 1, 6 and 7.

Fallen describes a device to support and display interrelated medical components, such as cardiopulmonary by-pass circuit components. Presently amended claim 1 incorporates the limitations of original claim 4, which was not rejected over Fallen and which has now been cancelled. Applicants respectfully submit that, with the present claim amendments, Fallen anticipates no pending claim. The remaining rejected claims 2, 3 and 6-8 depend on claim 1 and are allowable.

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Response to Examiner's Response

The Examiner bases the present rejections, particularly Bilstad II, on the premise "[i]f the prior art structure is capable of performing the intended use then it meets the claim." The Examiner relies on In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Both of these cases refused to consider the preamble to add patentable merit to the claim.

In Casey, the CCPA refused to consider the preamble of the claims, because the preamble did not "expressly or impliedly require any particular structure in addition to that of" the prior art. Casey, at 239. Here, the preambles of the presently rejected claims all expressly require particular structure that is neither taught by nor obvious from Bilstad II, Merte or Fallen, taken separately, together or in any combination with each other or other record references.

In regard to Otto, the MPEP remarks "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference ... between the claimed invention and the prior art. If so, the recitation serves to limit the claim." MPEP, § 211.02 Effect of Preamble, page 2100-49. In the present situation, the recited purpose and intended use of the claimed cartridge does indeed result in structural differences between the claimed invention and the disclosures of Bilstad II, Merte and Fallen, especially where the present claims are neither taught by nor obvious from the newly cited references, taken separately, together or in any combination with each other or other record references.

Note further that the Federal Circuit has recently provided certain guideposts to determining the effect of the preamble on claim scope. Catalina Mktg. Int'l v. Coolsavings.com, Inc. 62 USPQ2d 1781 (Fed. Cir. 2002).

"[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance

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on both the preamble and claim body to define the claimed invention. ... Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. ... Moreover, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."


Catalina, at 1784. Accordingly, the preambles of the present claims serve to define the meaning of the present claims and to define over all the art of record.

Conclusion

Applicants respectfully submit that this application is in condition for allowance and solicit a formal notice to that effect. Should any minor matters remain prior to the issuance of a notice of allowance, the undersigned attorney requests a telephone call from the Examiner to achieve prompt resolution thereof.

Respectfully submitted,

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